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August 27, 1998

FOOD AND DRUG ADMINISTRATION
Dockets Management Branch HFA-305
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857
Attn: Docket Number 95S-0158

Subject: BB IND-7371
Community consultation and public disclosure information
for waiver of Informed Consent.

To Dockets Management Branch:

Reference is made to our Investigational New Drug Application for Humanized Monoclonal Antibody Hu23F2G for Hemorrhagic Shock, BB-IND 7371, which was originally submitted to the FDA Office of Therapeutics Research and Review on October 28, 1997. We also refer to:

- i) Protocol AHS02, entitled "Phase 2B Safety and Efficacy Study of Hu23F2G in Subjects with Hemorrhagic Shock" which was included in the original submission
- ii) The guidelines described in 21 CFR §312.54(a) which require that IRB information concerning public disclosure be submitted to Docket 95S-0158, for clinical investigations involving an exemption from informed consent under 21 CFR §50.24.

The purpose of this submission is to provide documentation (21 CFR §50.24(a)(7)(ii)) concerning public disclosures received from IRBs at sites that are conducting Protocol AHS02. There are currently no completed studies under BB IND-7371, therefore public disclosure of results are not available (21 CFR §50.24(a)(7)(iii)).

The following five IRBs have granted approval to enroll patients under waiver of Informed Consent. Waiver can be exercised only under conditions where Informed Consent is not possible because, the patient is unable to provide consent, and no legally authorized representative or family member can be contacted to provide Informed Consent within the therapeutic window during which the study drug must be administered.

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Committee on Investigations Involving Human Subjects

University of California - San Diego

La Jolla, CA

Committee for the Protection of Human Subjects

University of Texas - Houston Medical School

Houston, TX

Human Subjects Review Committee

University of Washington

Seattle, WA

University of Pittsburgh Institutional Review Board

University of Pittsburgh

Pittsburgh, PA

UT Memphis Institutional Review Board

University of Tennessee - Memphis

Memphis, TN

If you have any comments or questions regarding this submission, please do not hesitate to contact me at (425) 485-1900, extension 2297.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Hesselberg", with a long horizontal flourish extending to the right.

Jeff Hesselberg, M.B.A.

Associate Director, Regulatory Affairs